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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,354	12/31/2003	Gregory Waimong Chan	5618P3473	1158

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/749,354

Applicant(s)

CHAN ET AL.

Examiner

Christopher D. Koharski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-12,17-19,21-28,33-53,56-58,63-85,87,89,90 and 92 is/are pending in the application.
- 4a) Of the above claim(s) 13-16,29-32, 47-50, 59-62,88 and 91 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-12,17-19,21-28,33-53,56-58,63-85,87,89,90 and 92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges amended claims 1-2, 5, 17, 33, 51, 56-57, 72-73, 78, 81-83, 85, 87, 89, 92 and 95, cancelled claims 4, 20, 54-55, 86, and 96, and withdrawn claims 13-16, 29-32, 47-50, 59-62, 88 and 91. Currently claims 1-3, 5-12, 17-19, 21-28, 33-53, 56-58, 63-85, 87, 89, 90 and 92 are currently pending for examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 33-38, 42-43, 45-46, 63, 65, and 92-95 are rejected under 35 U.S.C. 102(e) as being anticipated by Chow et al. (6,692,466).

Regarding claims 33-38, 42-43, 45-46, 63, 65 and 92-95, Chow et al. discloses an expandable body, multiple delivery cannulas, needle disposed in the cannulas, and a stop disposed in the lumen (Figure 4A). The stop comprising a sleeve coupled to the needle having a smaller diameter than the cannula (Figure 4B). The needle cannulas are attached to a hub present on the main body of the catheter (Figure 4A). A sheath ring (Figure 3C) is located around the expandable body and delivery cannulas. Chow et al. discloses a needle and hub system that has several different configurations and has a variable angle (Figure 1A). Chow et al. discloses an expandable body with at least one delivery cannula (Figure 1A) with a defined travel path. (Figure 2B). Wherein the needle has a proximal and distal portion coupled to each other (46 and 88) with different outside diameters. This transition point between two sections defines a step (Figure 4B). Chow et al. discloses a first and second cannula in fluid connection with a lumen (Figure 4A) used to penetrate a patients vascular system. Chow et al. discloses a device, which is inherently capable of performing the task of being positioned in the body and expanding the balloon member and delivering a treatment agent by advancing a needle via the needle stops and steering ribbon.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5-8, 11-12, 21-23, 17-19, 24, and 27-28 are rejected under 35 U.S.C 103(a) as being unpatentable over Chow et al. in view of Scarfone et al. (6,770,053). Chow et al. meets the claim limitations as described above except for a second lumen based stop.

However, Scarfone et al. teaches an endoscopic needle having dual distal stops.

Regarding claims 1-3, 5-8, 11-12, 21-23, 17-19, 24, and 27-28, Scarfone et al. teaches a needle cannula system that contains two stops (rearward and forward) to control the depth of the needle (Figures 2-3).

At the time of the invention, it would have been obvious to add an additional stop of Scarfone et al. with the system of Chow et al. to control the withdrawal distance of the needle within the needle system. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art

would have combined the teachings in the references in light of the disclosure of Scarfone et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-6, 9-10, 20-23, 25-26, 44, 56, 82-83 are rejected under 35 U.S.C 103(a) as being unpatentable over Chow et al. in view of Scarfone et al. in further view of Epstein et al. (6,835,193). The modified Chow et al. meets the claim limitations as described above but does not include a second stop in the lumen configuration.

However, Epstein et al. teaches a device for controlled injections. Regarding claims 5-6, 9-10, 20-23, 25-26, 44, 56, 82-83, Epstein et al. teaches a needle cannula system with multiple sleeves to stop the needle (both proximal and distal) and the partial sleeve changing the cross sectional shape (Figure 3). Epstein et al. teaches a second protuberance that limits the total movement of the needle and provides an orientation within the lumen. Chow et al. discloses a ribbon located in the lumen on the needle cannula (Figure 2A).

At the time of the invention, it would have been obvious to use the needle stop system of Epstein et al. with the needle stop system of Chow et al. because the addition of the second stop provides more precise control over the needle puncture depth. Both references are analogous in the art and with the instant invention; therefore, a

combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Epstein et al.

Claim Rejections - 35 USC § 103

Claims 25-28, 51-53, 56-58, 67-83, 85, and 89-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chow et al. in view of Scarfone et al. in further view of Flaherty et al. (2004/0133154). The modified Chow et al. meets the claim limitations as described above but does not include a proximal needle protuberance.

However, Flaherty et al. teaches a device for systems and methods for deliveries drugs to selected location within the body.

Regarding claims 25-28, 51-53, 56-58, 67-83, 85, and 89-90, Flaherty et al. teaches a protuberance on the proximal end of the needle that interacts with the hub to limit movement (Figure 1E). The protuberance is coupled to the needle portion to allow for a specified distance of movement through the hub.

At the time of the invention, it would have been obvious to use protuberance of Flaherty et al. with the system of Chow et al. because the addition of the second stop provides more precise control over the needle puncture depth. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Flaherty et al.

Claim Rejections - 35 USC § 103

Claims 39-41 and 84 are rejected under 35 U.S.C 103(a) as being unpatentable over Chow et al. Chow et al. discloses the claimed invention but does not disclose

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expressly the distance between the cannula and sheath ring, balloon adhered by adhesive made of cyanacrylate, needle composed of super elastic alloy. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the system of Chow et al. with the materials and dimensions as claimed by Applicant, because Applicant has not disclosed that the materials, adhesive bonding or distance provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a seem-less or bonded design as taught by Chow et al., because it provides a one-piece design for easier construction and more biocompatibility compared to cyanoacrylate adhesive, use of super elastic alloys (Chow et al. discloses a ribbon member made of various elastic materials) and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Chow et al.

Therefore, it would have been an obvious matter of design choice to modify Chow et al. to obtain the invention as specified in the claims.

Claim Rejections - 35 USC § 103

Claims 64 and 66 are rejected under 35 U.S.C 103(a) as being unpatentable over Chow et al. in view of Jacobson et al. (6,302,870). Chow et al. meets the claim limitations as described above but does not include the use of nickel-titanium alloy.

However, Jacobson et al. teaches an apparatus for injection into the walls of patient vessels. Regarding claims 64 and 66 Jacobson et al. teaches the use of nickel-

titanium alloys and other composites to achieve appropriate strength to accomplish the insertion task (col 3).

At the time of the invention, it would have been obvious to use construction materials of Jacobsen et al. with the system of Chow et al. because the addition of increased strength of materials provides the user with increased penetration and ease of use through the patient's body. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Jacobsen et al.

Response to Arguments

Applicant's arguments filed 6/12/2006 have been fully considered but they are not persuasive. Regarding claim 63, Chow et al. discloses multiple cannulas (Figure 1A, Figure 4B) with piercing and dispensing elements located with an attached cannula member cannula (86, 46) with a tip (52) and a allows for a continuous lumen for delivery.

Applicant's arguments with respect to claims 1, 17, 33, 51, 72, 78, and 92 have been considered but are moot in view of the new ground(s) of rejection necessitated by Applicant's amendment (see above rejection).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 7/13/2016


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